Charge Questions for SDMAC Therapeutic Distribution Subcommittee

November 13, 2020

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The COVID-19 pandemic has revealed the importance of developing and implementing protocols for the distribution of scarce therapeutics in possession of the state. Any distribution mechanism should be consistent with the ethical framework developed by SDMAC adopted by DHS and readily implementable to avoid unnecessary delays in treatment.

Assumptions:

- Novel therapeutics released under an emergency use authorization may not be sufficiently researched to know with certainty which patients are most likely to benefit.

- Therapeutics may be received in quantities that are unpredictable. This may result in situations of temporary scarcity.

Charge:

1. For distribution of therapeutics **in possession of the state**, describe the potential approaches for distribution by DHS. Consider any practical concerns that may impact efficient distribution. The Subcommittee should consider, at a minimum, the following approaches and describes the benefits and limitations of each.

    - *Distribution by geography*: Therapeutics in possession of the state could be distributed on a geographic basis (e.g., county, region) based upon size of population, burden of disease, and/or by weighting for baseline health disparities. The geographic unit of distribution may be a county (smallest) or region (largest), with subsequent distribution decisions made by receiving party.

        - *Targeted approach? i.e. "hot spot"*

            - Utility of medication as a public health tool

            - Direct therapy to a specific area

            - Would need evidence that supports medication as extremely effective (i.e. prevents hospitalization, severe disease, etc.)

            - Equity to communities and historical/existing approach to mitigation strategies (i.e. accounting for communities that are intentionally noncompliant with public health recommendations)

                - Ethical concerns

                    - Is community disadvantaged in a way that makes public health recommendations difficult to comply with? Lack of capability versus accountability?

                    - How do we account for sub-communities in each community?

                    - Strive to focus on objective data, evidence-based recommendations

- *Central distribution hub*?
  Ex: State has a significant allotment, distributive hub in each region (i.e. county), each hospital runs its lottery (all sites would randomize the same way), facility notifies the hub, then the medication is transferred over to the sites
    - *Benefits*
        - More equitable
        - Allows for micro-allocation
    - *Obstacles/barriers*
        - Would need appropriate lead time- mechanism of action of the medication would influence this
        - Logistical concerns
        - State would need to determine lottery weightings, potentially data utilized within randomization

- *Distribution by facility*: Therapeutics could be distributed to healthcare facilities or systems, local public health departments, or outpatient clinics based upon disease burden in the community or within a particular institution.

- *Distribution to individual patients*: Therapeutics could be distributed to individual patients via random allocation for those meeting clinical criteria for treatment as defined by FDA authorization. Alternatively, therapeutics could be distributed to a subset of patients that have been identified in published research as being most likely to benefit. Note: distribution to individual patients by DHS may be impractical for large quantities of medication or if complex clinical criteria must be considered.
    - *How do you access individuals who are not in the health system*?
    - *How do you connect early enough to individuals who have test results*?
        - *Miller Park testing*- where is this information reported to?
            - Data is fed through Public Health department- information flows between county public health department and state
            - How does timing factor in?

- *Brainstorming: Oral therapy situation (i.e. tablet, capsule, PO liquid)*
    - Is it a single dose?
        - If yes, broader possibilities
        - If no, will limit options
    - PODs (Points of Dispensing)
        - Would help account for individuals not linked to a health system

- Analog to community testing sites, think of a community treatment site
- Workforce needed? Who would staff this

2. Other allocation approaches not described above (e.g., weighted lottery) may be discussed and considered by the Subcommittee. As the conclusion of deliberations, the Subcommittee will recommend an approach for distribution of therapeutics in possession of the state. If more than one approach is considered acceptable, describe the situations and circumstances in which one approach may be favored over another.

- Step-wise/Tiered approach by patient risk factors/criteria
    - Similar to ventilator approach
    - Health-systems already utilize this approach locally when supply is limited i.e. remdesivir prior to FDA approval

3. Of the approach(es) recommended by the Subcommittee, devise a generic algorithm that can be utilized by DHS to distribute therapeutics.

4. For institutions that may receive a supply of therapeutics, briefly describe how the ethical principles from the SDMAC ethical framework should be considered when allocating to patients.

October 10, 2020

Questions related to allocation of therapeutics obtained and distributed by healthcare institutions are out of scope of the Subcommittee's work.

Work Plan:

The charge questions and work plan for the Subcommittee have been approved by the DHS Secretary's Office.

The DPH Chief Medical Officers have invited stakeholders and subject matter experts from a range of backgrounds to participate in the subcommittee.

The subcommittee chair will decide the order in which the questions will be addressed, and prepare an agenda and/or draft document prior to meetings to facilitate discussion.

The work will continue for an anticipated 4-6 weeks, culminating in a written report that provides recommendations for a strategic framework to be adopted by DHS, along with the relevant considerations for modifications and future decisions that cannot be addressed given current knowledge.